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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/283,318	03/31/1999		JACK V. SMITH	9827	
75	90	05/07/2002			
JACK V SMI	ГН		EXAMINER		
PO BOX 5895			FOLEY, SHANON A		
ASHEVILLE, NC 28813				1 obb 1, om intorn	
				ART UNIT	PAPER NUMBER
				1648	
				DATE MAILED: 05/07/2002	10

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	A == 1: = = = 4(a)					
1	•	Application No.	Applicant(s)					
•	Office Action Summary	09/283,318	SMITH, JACK V.					
	Office Action Guilliary	Examiner	Art Unit					
<u>.</u>	The MAILING DATE of this communication an	Shanon A. Foley	1648					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
THE I - Exter after - If the - If NO - Failur - Any n	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. Isions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a repl period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailin d patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however by within the statutory mining will apply and will expire SI a, cause the application to the	er, may a reply be timely filed num of thirty (30) days will be considered timely. X (6) MONTHS from the mailing date of this communic tecome ABANDONED (35 U.S.C. § 133).	ation.				
1)	Responsive to communication(s) filed on <u>06</u>	February 2002 .						
2a)□		nis action is non-fin	al.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims							
4)⊠	4)⊠ Claim(s) 5,8 and 19-32 is/are pending in the application.							
4a) Of the above claim(s) 5 and 8 is/are withdrawn from consideration.								
5)□	5) Claim(s) is/are allowed.							
6)	Claim(s) is/are rejected.							
7)	Claim(s) is/are objected to.							
•	Claim(s) <u>19-32</u> are subject to restriction and/o	r election requirem	ent.					
· · _	on Papers							
•	The specification is objected to by the Examine		er la dia E acciona					
10)[	The drawing(s) filed on is/are: a)□ acce	•	•					
111	Applicant may not request that any objection to the							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. §§ 119 and 120								
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) ☐ All b) ☐ Some * c) ☐ None of:								
1. Certified copies of the priority documents have been received.								
	2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.								
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).								
a) The translation of the foreign language provisional application has been received.								
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.								
Attachment(s)								
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) 🔲 🖠	nterview Summary (PTO-413) Paper No(s) Notice of Informal Patent Application (PTO-152) Other:	<u> </u>				

Application/Control Number: 09/283,318

Art Unit: 1648

## **DETAILED ACTION**

In the amendment filed 2/6/2 in paper no. 14, applicant deleted claims 11-18 and added new claims 19-32. Claims 5, 8, and 19-32 are pending in the application. Claims 5 and 8 remain withdrawn from consideration due to a non-election of invention and claims 19-32 are under consideration. Applicant is reminded to cancel claims 5 and 8. The new claims comprise several patentably distinct inventions that are outside the scope of what was previously examined and a restriction requirement is deemed necessary.

It is noted that the claims have been amended to recite, "without the use of Western Blot, and Thin Layer Liquid Phase methods". These negative limitations cannot be found in the original disclosure. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). It is suggested that applicant cancel the new matter in order to avoid a rejection under 35 U.S.C. § 112, first paragraph.

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 19-22, drawn to a method of detecting the presence of HIV antibodies, classified in class 435, subclass 5.
- II. Claims 23-29, drawn to a method of detecting the presence of HIV antibodies,classified in class 435, subclass 5.
- III. Claims 30-32, drawn to a method of detecting the presence of HIV antibodies, classified in class 435, subclass 5.

Application/Control Number: 09/283,318

Art Unit: 1648

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The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions use different reagents, method steps, and indicators to determine the presence of HIV antibodies in a test sample. The method of group I requires the use of IgG antibody, HIV antigen and IgG conjugated to microparticles and an HIV antibody, which are impregnated in three steps. Group II requires the use of HIV antigen conjugated to an enzyme and an indicator substrate complex. These ingredients are not required for group I or III. Group III requires IgG antibody and IgG conjugated to microparticles and does not require the HIV antigen conjugated to microparticles or HIV antigen in group I, or the ingredients of group II. The different reagents and ingredients used in each of the distinct methods denote different mechanisms for determining whether or not HIV antibodies are present in a sample.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, the search required for group II is not required for I, III, the search for group III is not overlapping with groups I, II, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Application/Control Number: 09/283,318

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF May 6, 2002

JAMES HOUSEL

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTED 1000